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EXAMINER	
DORNBUSCH, DIANNE	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
03/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/724,021	ORR ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2010*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-13 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-13 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 26, 2011 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5, 9-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perier (4,863,072) in view of Ritcher et al. (4,232,670) and further in view of DiBenedetto et al. (7,727,542).

Claims 1-3:

Perier discloses a first component (12) for receiving and dispensing the tissue scaffold having a proximal end, a distal end, and an elongate, hollow body extending therebetween (Fig. 1-2), the elongate body defining a passageway extending from the proximal end to the distal end (Fig. 1-2); and a second component (14) having an elongate body (Fig. 2 and 6) with a blunt tip (48) at a distal end (Fig. 2 and 6), the tip

having a diameter less than the diameter of the elongated body (Fig. 2 and 6), the elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 1 and 7), the second component including at least one sealing ring (23) around the elongate body proximal to the tip (Fig. 2 and 5).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Perier teaches all the claimed limitations discussed above however, Perier does not disclose that the first component has a funnel shaped proximal end.

Ritcher discloses a first component (combination of 10, 20, and 40) with a funnel shaped proximal end (40) as seen in Fig. 1. Ritcher further discloses that the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 1) and that the first, flared portion has a curved tapered shape (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Perier with a funnel shaped proximal end in view of the teachings of Ritcher, in order to simplify the filling of the first component by using a funnel which would prevent spilling.

Perier in view of Ritcher teaches all the claimed limitations discussed above however, Perier in view of Ritcher does not disclose a tissue scaffold.

DiBenedetto discloses a tissue scaffold (Col. 9 Lines 4-19) which is injected in the body by using a syringe (Col. 4 Lines 19-33 and 39-40 and Col. 9 Lines 4-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a syringe as the one taught by Perier in view of Ritcher to deliver the tissue scaffold of DiBenedetto since it can be delivered with a variety of syringes (Col. 4 Lines 19-33).

Claims 4 and 15: Perier in view of Ritcher and DiBenedetto discloses the claimed invention except for the diameter of the flared portion is between 15 to 50 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a diameter of the flared portion is between 15 to 50 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 5: Perier in view of Ritcher and DiBenedetto discloses the claimed invention except for the diameter of the tubular portion is between 5 to 17 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a diameter of the tubular portion is between 5 to 17 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 9-11:

Perier discloses a first component (12) for receiving and dispensing the tissue scaffold having a proximal end, a distal end, and an elongate, hollow body extending therebetween (Fig. 1-2), the elongate body defining a passageway extending from the proximal end to the distal end (Fig. 1-2); and a second component (14) having an elongate body (Fig. 2 and 6) with a blunt tip (48) at a distal end (Fig. 2 and 6), the tip having a diameter less than the diameter of the elongated body (Fig. 2 and 6), the elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 1 and 7), the second component including at least one sealing ring (23) around the elongate body proximal to the tip (Fig. 2 and 5).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Perier teaches all the claimed limitations discussed above however, Perier does not disclose that the insertion rod further includes a pair of sealing rings around the elongate body.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have a second sealing ring since the examiner is taking Official Notice that the use of a second sealing ring is well known in the art in order to

control the sliding resistance between the first components and the second component as well as providing a seal.

Perier teaches all the claimed limitations discussed above however, Perier does not disclose that the first component has a funnel shaped proximal end.

Ritcher discloses a first component (combination of 10, 20, and 40) with a funnel shaped proximal end (40) as seen in Fig. 1. Ritcher further discloses that the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 1) and that the first, flared portion has a curved tapered shape (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Perier with a funnel shaped proximal end in view of the teachings of Ritcher, in order to simplify the filling of the first component by using a funnel which would prevent spilling.

Perier in view of Ritcher teaches all the claimed limitations discussed above however, Perier in view of Ritcher does not disclose a tissue scaffold.

DiBenedetto discloses a tissue scaffold (Col. 9 Lines 4-19) which is injected in the body by using a syringe (Col. 4 Lines 19-33 and 39-40 and Col. 9 Lines 4-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a syringe as the one taught by Perier in view of Ritcher to deliver the tissue scaffold of DiBenedetto since it can be delivered with a variety of syringes (Col. 4 Lines 19-33).

Claim 12: Perier in view of Ritcher and DiBenedetto discloses the claimed invention except for the diameter of the tubular portion is between 6 to 17 mm. It would have

been obvious to one having ordinary skill in the art at the time the invention was made to have a diameter of the tubular portion is between 6 to 17 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 13: Perier in view of Ritcher and DiBenedetto discloses all the claimed limitations discussed above except the second, tubular portion has a diameter in the range of about 7 mm to about 9 mm. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Perier in view of Ritcher and DiBenedetto with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

4. Claims 1-5, 9-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perier (4,863,072) in view of Evans et al. (2004/0204715) and further in view of DiBenedetto et al. (7,727,542).

Claims 1-5:

Perier discloses a first component (12) for receiving and dispensing the tissue scaffold having a proximal end, a distal end, and an elongate, hollow body extending therebetween (Fig. 1-2), the elongate body defining a passageway extending from the proximal end to the distal end (Fig. 1-2); and a second component (14) having an elongate body (Fig. 2 and 6) with a blunt tip (48) at a distal end (Fig. 2 and 6), the tip having a diameter less than the diameter of the elongated body (Fig. 2 and 6), the

elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 1 and 7), the second component including at least one sealing ring (23) around the elongate body proximal to the tip (Fig. 2 and 5).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Perier teaches all the claimed limitations discussed above however, Perier does not disclose that the first component has a funnel shaped proximal end.

Evans discloses a first component (300) having a funnel-shaped proximal end (320), a distal end (330), and an elongate, hollow body (310) extending therebetween (Fig. 2), wherein the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 5); wherein the first, flared portion has a curved tapered shape (Fig. 2 and 5); wherein the flared proximal end of the first component has a diameter in the range of about 15 mm to about 50 mm ([0048]); and wherein the second, tubular portion has a diameter in the range of about 5 mm to about 17 mm ([0042]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to substitute the first component of Perier with the funnel shaped first component of Evans, in order to simplify the filling of the first component by using a funnel which would prevent spilling.

Perier in view of Evans teaches all the claimed limitations discussed above however, Perier in view of Evans does not disclose a tissue scaffold.

DiBenedetto discloses a tissue scaffold (Col. 9 Lines 4-19) which is injected in the body by using a syringe (Col. 4 Lines 19-33 and 39-40 and Col. 9 Lines 4-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a syringe as the one taught by Perier in view of Evans to deliver the tissue scaffold of DiBenedetto since it can be delivered with a variety of syringes (Col. 4 Lines 19-33).

Claims 9-12 and 15:

Perier discloses a first component (12) for receiving and dispensing the tissue scaffold having a proximal end, a distal end, and an elongate, hollow body extending therebetween (Fig. 1-2), the elongate body defining a passageway extending from the proximal end to the distal end (Fig. 1-2); and a second component (14) having an elongate body (Fig. 2 and 6) with a blunt tip (48) at a distal end (Fig. 2 and 6), the tip having a diameter less than the diameter of the elongated body (Fig. 2 and 6), the elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 1 and 7), the second component including at least one sealing ring (23) around the elongate body proximal to the tip (Fig. 2 and 5).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art

apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Perier teaches all the claimed limitations discussed above however, Perier does not disclose that the insertion rod further includes a pair of sealing rings around the elongate body.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have a second sealing ring since the examiner is taking Official Notice that the use of a second sealing ring is well known in the art in order to control the sliding resistance between the first components and the second component as well as providing a seal.

Perier teaches all the claimed limitations discussed above however, Perier does not disclose that the first component has a funnel shaped proximal end.

Evans discloses a first component (300) having a funnel-shaped proximal end (320), a distal end (330), and an elongate, hollow body (310) extending therebetween (Fig. 2), wherein the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 5); wherein the first, flared portion has a curved tapered shape (Fig. 2 and 5); wherein the flared proximal end of the first component has a diameter in the range of about 15 mm to about 50 mm ([0048]); and wherein the second, tubular portion has a diameter in the range of about 5 mm to about 17 mm ([0042]).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to substitute the first component of Perier with the funnel

shaped first component of Evans, in order to simplify the filling of the first component by using a funnel which would prevent spilling.

Perier in view of Evans teaches all the claimed limitations discussed above however, Perier in view of Evans does not disclose a tissue scaffold.

DiBenedetto discloses a tissue scaffold (Col. 9 Lines 4-19) which is injected in the body by using a syringe (Col. 4 Lines 19-33 and 39-40 and Col. 9 Lines 4-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a syringe as the one taught by Perier in view of Evans to deliver the tissue scaffold of DiBenedetto since it can be delivered with a variety of syringes (Col. 4 Lines 19-33).

Claim 13: Perier in view of Evans and DiBenedetto discloses all the claimed limitations discussed above except the second, tubular portion has a diameter in the range of about 7 mm to about 9 mm. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Perier in view of Evans and DiBenedetto with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

5. Claims 9-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masano (5,221,348) in view of Ritcher et al. (4,232,670) and further in view of DiBenedetto et al. (7,727,542).

Claims 9-11:

Masano discloses a first component (2) for receiving and dispensing the tissue scaffold having a proximal end, a distal end, and an elongate, hollow body extending therebetween (Fig. 2b), the elongate body defining a passageway extending from the proximal end to the distal end (Fig. 2b); and a second component (3) having an elongate body (12) with a blunt tip (25) at a distal end (Fig. 1), the tip having a diameter less than the diameter of the elongated body (Fig. 1) the elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 1), the second component including a pair of sealing rings (23 and 24) around the elongate body proximal to the tip (Fig. 1).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Masano teaches all the claimed limitations discussed above however, Masano does not disclose that the first component has a funnel shaped proximal end.

Ritcher discloses a first component (combination of 10, 20, and 40) with a funnel shaped proximal end (40) as seen in Fig. 1. Ritcher further discloses that the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 1) and that the first, flared portion has a curved tapered shape (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Masano with a funnel shaped proximal end in view of the teachings of Ritcher, in order to simplify the filling of the first component by using a funnel which would prevent spilling.

Masano in view of Ritcher teaches all the claimed limitations discussed above however, Masano in view of Ritcher does not disclose a tissue scaffold.

DiBenedetto discloses a tissue scaffold (Col. 9 Lines 4-19) which is injected in the body by using a syringe (Col. 4 Lines 19-33 and 39-40 and Col. 9 Lines 4-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a syringe as the one taught by Masano in view of Ritcher to deliver the tissue scaffold of DiBenedetto since it can be delivered with a variety of syringes (Col. 4 Lines 19-33).

Claim 12: Masano in view of Ritcher and DiBenedetto discloses the claimed invention except for the diameter of the tubular portion is between 6 to 17 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a diameter of the tubular portion is between 6 to 17 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 13: Masano in view of Ritcher and DiBenedeto discloses all the claimed limitations discussed above except the second, tubular portion has a diameter in the range of about 7 mm to about 9 mm. It would have been obvious to a person having

ordinary skill in the art at the time the invention was made to provide Masano in view of Ritcher with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 15: Masano in view of Ritcher and DiBenedetto discloses the claimed invention except for the diameter of the flared portion is between 15 to 50 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a diameter of the flared portion is between 15 to 50 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

6. Claims 1-7, 9-13, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Discko, Jr. (5,324,273) in view of Ritcher et al. (4,232,670) and further in view of DiBenedetto et al. (7,727,542.

Claims 1-3 and 6:

Discko discloses a first component (10) for receiving and dispensing the tissue scaffold having a proximal end, a distal end, and an elongate, hollow body extending therebetween (Fig. 3), the elongate body defining a passageway extending from the proximal end to the distal end (Fig. 3); and a second component (26) having an elongate body (Fig. 1) with a blunt tip (30) at a distal end (Fig. 1), the tip having a diameter less than the diameter of the elongated body (Fig. 1 where the tip is tapered to a smaller diameter), the elongate body being configured to be removably disposed

within the first component for sliding along the passageway (Fig. 3), the second component including at least one sealing ring (28) around the elongate body proximal to the tip (Fig. 1). Discko further discloses that the tip of the second component comprises a spherical tip (Fig. 1).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Discko teaches all the claimed limitations discussed above however, Discko does not disclose that the first component has a funnel shaped proximal end.

Ritcher discloses a first component (combination of 10, 20, and 40) with a funnel shaped proximal end (40) as seen in Fig. 1. Ritcher further discloses that the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 1) and that the first, flared portion has a curved tapered shape (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Discko with a funnel shaped proximal end in view of the teachings of Ritcher, in order to simplify the filling of the first component by using a funnel which would prevent spilling.

Discko in view of Ritcher teaches all the claimed limitations discussed above however, Discko in view of Ritcher does not disclose a tissue scaffold.

DiBenedetto discloses a tissue scaffold (Col. 9 Lines 4-19) which is injected in the body by using a syringe (Col. 4 Lines 19-33 and 39-40 and Col. 9 Lines 4-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a syringe as the one taught by Discko in view of Ritcher to deliver the tissue scaffold of DiBenedetto since it can be delivered with a variety of syringes (Col. 4 Lines 19-33).

Claims 4 and 15: Discko in view of Ritcher and DiBenedetto discloses the claimed invention except for the diameter of the flared portion is between 15 to 50 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a diameter of the flared portion is between 15 to 50 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 5: Discko in view of Ritcher and DiBenedetto discloses the claimed invention except for the diameter of the tubular portion is between 5 to 17 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a diameter of the tubular portion is between 5 to 17 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 7, 17, and 18: Discko in view of Ritcher and DiBenedetto teaches all the claimed limitations discussed above however, Discko in view of Ritcher and DiBenedetto does

not disclose that the spherical tip has a diameter in the range of about 6 mm to about 10 mm and more specifically between 6-8 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Discko with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (11)

Claims 9-11 and 16:

Discko discloses a first component (10) for receiving and dispensing the tissue scaffold having a proximal end, a distal end, and an elongate, hollow body extending therebetween (Fig. 3), the elongate body defining a passageway extending from the proximal end to the distal end (Fig. 3); and a second component (26) having an elongate body (Fig. 1) with a blunt tip (30) at a distal end (Fig. 1), the tip having a diameter less than the diameter of the elongated body (Fig. 1 where the tip is tapered to a smaller diameter), the elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 3), the second component including at least one sealing ring (28) around the elongate body proximal to

the tip (Fig. 1). Discko further discloses that the tip of the second component comprises a spherical tip (Fig. 1).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Discko teaches all the claimed limitations discussed above however, Discko does not disclose that the insertion rod further includes a pair of sealing rings around the elongate body.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have a second sealing ring since the examiner is taking Official Notice that the use of a second sealing ring is well known in the art in order to control the sliding resistance between the first components and the second component as well as providing a seal.

Discko teaches all the claimed limitations discussed above however, Discko does not disclose that the first component has a funnel shaped proximal end.

Ritcher discloses a first component (combination of 10, 20, and 40) with a funnel shaped proximal end (40) as seen in Fig. 1. Ritcher further discloses that the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 1) and that the first, flared portion has a curved tapered shape (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Discko with a funnel shaped proximal end in view of the teachings of Ritcher, in order to simplify the filling of the first component by using a funnel which would prevent spilling.

Discko in view of Ritcher teaches all the claimed limitations discussed above however, Discko in view of Ritcher does not disclose a tissue scaffold.

DiBenedetto discloses a tissue scaffold (Col. 9 Lines 4-19) which is injected in the body by using a syringe (Col. 4 Lines 19-33 and 39-40 and Col. 9 Lines 4-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a syringe as the one taught by Discko in view of Ritcher to deliver the tissue scaffold of DiBenedetto since it can be delivered with a variety of syringes (Col. 4 Lines 19-33).

Claim 12: Discko in view of Ritcher and DiBenedetto discloses the claimed invention except for the diameter of the tubular portion is between 6 to 17 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a diameter of the tubular portion is between 6 to 17 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 13: Discko in view of Ritcher and DiBenedetto discloses all the claimed limitations discussed above except the second, tubular portion has a diameter in the range of about 7 mm to about 9 mm. It would have been obvious to a person having ordinary skill

in the art at the time the invention was made to provide Discko in view of Ritcher and DiBenedetto with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

7. Applicant's arguments with respect to claims 1-7, 9-13, and 15-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited art all teach a tissue scaffold which is injected into the body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Dianne Dornbusch/
Examiner, Art Unit 3773